**From:** Durand, Nancy S
**To:** Lisa Holmes; Jennifer Clark; Connie McDonough
**CC:** ONC Reimbursement; Peter T Benavente
**Sent:** 5/31/2012 8:31:49 PM
**Subject:** RE: Arzerra CI
**Attachments:** ATT00001..txt; ATT00002..htm; OIG Ruling.pdf; OIG_Anti-Kick Back Statute.pdf

Hi Everyone:

Please see the attached slide show and PAP Compliance for Manufacturers doc.

Best,
Nancy

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**From:** Lisa Holmes [mailto:Lisa.Holmes@tevapharm.com]
**Sent:** Wednesday, May 30, 2012 4:09 PM
**To:** Jennifer Clark; Durand, Nancy S; Connie McDonough
**Cc:** ONC Reimbursement; Peter T Benavente
**Subject:** RE: Arzerra CI

Jennifer, It is interesting they throw it out there, but then pull it back in the criteria. In fact, Arzerra is not available generically. I appreciate any other clarification we can get from you, Nancy. Thanks.

*Lisa Holmes*
*Senior Director, Reimbursement*
*Oncology Business Unit*
*Teva Pharmaceuticals*
*Office 610-727-6309*
*Mobile 610-766-1168*
*Fax 610-727-6150*

lisa.holmes@tevapharm.com

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**From:** Jennifer Clark
**Sent:** Tuesday, May 29, 2012 10:49 AM
**To:** Durand, Nancy S; Lisa Holmes; Connie McDonough
**Cc:** ONC Reimbursement; Peter T Benavente
**Subject:** RE: Arzerra CI

This is the first I've ever heard of anything like this. However, I did notice on their website (under 'Other Criteria') that the patient cannot have prescription drug benefits, unless the coverage is limited to generic prescription medicine only. Do we know if Arzerra is only available as a branded product?

I'll check with our legal to see if they can shed any light on this as well.

**Jennifer Clark, CPA** Sr. Manager, Patient Services & Reimbursement
Tel: (816) 508-5396 Cell: (816) 332-2873 Fax: (816) 508-5589
Jennifer.Clark@tevapharm.com sip:Jennifer.Clark@tevapharm.com www.tevapharm.com

**From:** Durand, Nancy S [mailto:Nancy.Durand@ACCESSMED.COM]
**Sent:** Friday, May 25, 2012 2:40 PM
**To:** Lisa Holmes; Connie McDonough; Jennifer Clark
**Cc:** ONC Reimbursement; Peter T Benavente
**Subject:** RE: Arzerra CI

Hi Everyone:

The attached opinion is from 2006. Let me see if I can dig up anythng more current from OIG on Part B/D. I ran this question by, Steve Chan recently on behalf of our ORS team. BTW Steve is the one who worked with Rich & I on the FRM Toolkit.

In addition to the attached he also shared this from his team:

While the below info is not directly related it suggests that at the time of this opinion, they had not issued an opinion on Part B.

http://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf

"We are writing in response to your request for an advisory opinion regarding a pharmaceutical company patient assistance program that provides free outpatient prescription drugs to financially-needy Medicare Part D enrollees entirely outside of the Part D benefit (the "Arrangement")"

"As we observed in our recent Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (70 Fed. Reg. 70623 (November 22, 2005)), manufacturer PAPs that subsidize the cost-sharing amounts for the manufacturer's drugs payable in whole or in part by the Part D program present all of the usual risks of fraud and abuse associated with kickbacks, including steering enrollees to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing enrollees' incentives to locate and use less expensive, equally effective drugs."

"However, in this case, the Requestor operates the PAPs entirely outside of the Part D benefit. Operating outside of the Part D benefit means the enrollees obtain their drugs without using their Part D insurance benefit. No claims for payment for the drugs provided outside the Part D benefit are filed with a Part D plan or the beneficiary, and the assistance does not count toward the enrollee's TrOOP or total Part D spending for any purpose. Having reviewed the Arrangement, we conclude that the Arrangement contains safeguards sufficient to ensure that the PAPs operate entirely outside the Part D benefit, and, therefore, there is minimal risk of fraud and abuse under the Part D program."

"In addition, we caution that we might reach a different result were we to evaluate an arrangement similar to the Arrangement arising other than in the Part D context."

"Many of the uses of these drugs involve physician administration and coverage under Medicare Part B. The Arrangement is limited to the uses of these drugs that are eligible for coverage under Medicare Part D, without regard to whether or not an individual enrollee's Part D plan actually covers that drug. PAP A does not provide free drugs to Medicare beneficiaries for uses that are eligible for coverage under Medicare Part B."

Here is the link to the Arzerra Program:

http://www.commitmenttoaccess.com/enrollment/eligibility-arzerra.html

**Eligibility Criteria for Patients Taking ARZERRA™**

Patients with prescription drug benefits through Medicare Part B or through a commercial plan may be eligible for COMMITMENT TO ACCESS® when they have a copayment that exceeds $2,000, subject to other criteria. Advocates may call 1-8ONCOLOGY1 (1-866-265-6491) for more information.

Well, it's a start.

Best,

**Nancy**

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**From:** Lisa Holmes [mailto:Lisa.Holmes@tevapharm.com]
**Sent:** Friday, May 25, 2012 12:18 PM
**To:** Connie McDonough; Durand, Nancy S; Jennifer Clark
**Cc:** ONC Reimbursement; Peter T Benavente
**Subject:** Re: Arzerra CI

Nancy and Jennifer
Will you get some advice from your network...any knowledge of an OIG opinion allowing access to copay assistance for Medicare pts?

Lisa Holmes

On May 25, 2012, at 11:03 AM, "Connie McDonough" <Connie.McDonough@tevapharm.com> wrote:

One of my WI customers told me that there was both a commercial and Medicare copay assist for arzerra directly. Patient copay for commercial capped at 100 and Medicare 400. I got the impression that GSK had gone through a special government approval of the Medicare program FYI.

*Connie K. McDonough, RN, MSN*
*Field Reimbursement Manager*
*Teva Oncology*
*connie.mcdonough@tevapharm.com*
*cell: 302-824-4189*

SIDLEY AUSTIN

SIDLEY

Legal Considerations in Developing Patient Assistance Programs
September 19, 2008

Perry Knight, MHA, JD
pknight@sidley.com
(202) 736-8256

## Agenda

- Overview of Fraud & Abuse Laws
- Key PAP Risk Areas Identified by the OIG
- Price Reporting Considerations
- Other Considerations
- Questions



## Federal Anti-Kickback Statute (AKS)
(42 USC 1320a-7b(b))

**Prohibits any person from knowingly and willfully soliciting, offering, paying, or receiving any remuneration in return for making referrals or otherwise generating business for which payment may be made under federal or state health care programs.**

- AKS applies to "any person" who gives, receives, offers, or solicits remuneration
  - Applies to both sides of the transaction and anyone in between
- Remuneration is defined broadly to include *anything of value*, including discounts and free items or services

> "Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the antikickback statute is violated." OIG, SAB

## Federal Anti-Kickback Statute ("AKS")

- "One purpose" test
  - If even one purpose of remuneration is to induce referrals, the statute is violated, regardless of other beneficial purposes
- Applies only where payment may be made under a Federal or State health care program.
- Violation is a felony. Penalties include:
  - Maximum $25,000 fine
  - 5 years imprisonment (or both)
  - Exclusion from Federal health care programs.
- Violation may also trigger civil monetary penalties.

**Intended to prevent financial considerations from interfering with:**

- Medical decision-making
- Choice of Provider
- Amount of medical care provided



## Civil Monetary Penalties

(42 USC 1320a-7a(a)(5))

- "Any person... that— ... offers to or transfers remuneration to any individual eligible for benefits under [Medicare], or under a State health care program... [e.g., Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [such program]... shall be subject ... to a civil money penalty of not more than $10,000 for each item or service ... . In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service.... In addition the Secretary may make a determination...to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1))and to direct the appropriate State agency to exclude the person from participation in any State health care program."
- "Remuneration" defined to include waiver of coinsurance and deductibles and "transfers of items or services for free or for other than fair market value."



## Department of Health and Human Services Office of the Inspector General ("OIG")

- OIG polices fraud & abuse concerns
- Investigate internal (HHS) and external arrangements for fraud & abuse concerns
- Issue Advisory Opinions ("AOs")
  - Can be requested by parties to a real transaction or parties intending in good faith to enter into an arrangement
  - Opinion speaks only to the specific factual situation
  - Can only be relied upon by the party seeking the Opinion
  - But can be important guidance for others

## OIG on PAPs

- Medicare Part D was a watershed event for PAP fraud & abuse guidance
  - Medicare Part D brought federal healthcare program funds into play for prescriptions filled for Medicare beneficiaries. This necessarily entailed AKS considerations.
  - PAPs still needed for un-enrolled individuals and costs in coverage gap.
  - Concern for TrOOP, use PAPs to "speed through" the coverage gap.
- Special Advisory Bulletin (SAB) November 2005
  - 70 Fed. Reg. 70623 (Nov. 22, 2005)
  - Addresses how PAPs can assist Medicare beneficiaries
  - Does not apply to PAPs assisting the uninsured



## OIG on PAPs

- "[P]harmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present **heightened risks** under the antikickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe **lawful avenues exist** for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs."



## OIG on PAPs

- Whether a PAP arrangement violates the AKS, requires a case-by-case analysis
  - "For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are necessarily relevant to the analysis." OIG, SAB
- PAPs raise two questions
  1. Does the subsidy count towards TrOOP?
     - Under CMS regulations yes, BUT
  2. Does the subsidy implicate the AKS?
     - "Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product." OIG, SAB
- PAPs present "all of the usual risks of fraud and abuse associated with kickbacks"
  - Steering patients to particular drugs
  - Increasing costs to Medicare
  - Providing financial incentives over competing drugs
  - Reducing enrollees' incentives to locate and use less expensive, equally effective drugs

## Medicare Part D PAP Options: "Inside Part D"

- *Bona Fide* Independent Charitable Foundation
  - Manufacturer donates money to independent charitable foundation
  - Foundation awards assistance to individuals
  - Assistance counts as TrOOP

"Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." OIG, SAB



## Medicare Part D PAP Options: "Inside Part D"

- Safeguards
  - Manufacturer exerts no influence or control over the program
  - Foundation awards assistance in a truly independent manner
  - Assistance awarded without regard to manufacturer interests or beneficiary choice of provider or Part D plan
  - Assistance based on "reasonable, verifiable, and uniform measure of financial need applied in a consistent manner" (flexibility permitted)
  - Manufacturer cannot solicit data to correlate donations with product use
  - Donations may be earmarked for broad disease categories - BUT
    - "[M]anufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products." OIG, SAB



## Medicare Part D PAP Options: "Inside Part D"

- Footnote:
  - "In-kind donations of drugs to independent charity PAPs pose additional risks not yet directly addressed in prior OIG guidance, and we have insufficient experience with them to offer detailed guidance here. While in-kind donations have the potential benefit of increasing the value of donations (because marginal costs of drugs are generally low), they also have the effect of creating a direct correlation between the donation and use of a particular donor's product, thereby weakening important safeguards of an independent charity PAP arrangement." OIG, SAB

## Medicare Part D PAP Options: "Outside Part D"

- Operates like a standard PAP
  - Patients apply directly to manufacturer (or agent)
  - Manufacturer determines eligibility requirements and manages application process
  - Manufacturer provides product to patients
    - Directly or through retail/mail-order pharmacies
  - Does not count as TrOOP
- Safeguards
  - Notify Part D plan
    - CMS Voluntary Data Sharing Agreement
  - Assistance provided for remainder of the coverage year
  - Assistance available even for periodic use
  - Accurate and contemporaneous records
  - Assistance based on "reasonable, verifiable, and uniform measure of financial need applied in a consistent manner"
  - Comply with CMS guidance



## Medicare Part D PAP Options: Bulk Replacement

- Bulk Replacement Programs
  - Difference between PAPs and bulk replacement is the more formal involvement of the provider (e.g., the hospital or clinic)
    - Creates a greater opportunity for inappropriate arrangements
    - Institutions have formulary power, can influence market share within their own house and potentially beyond

> "These programs potentially implicate the Federal anti-kickback statute if the free drugs are given to a recipient that is in a position to generate Federal health care program business for the donor manufacturer." OIG, SAB

  - Safeguards
    - Prevent steering based on the financial interests of their health care providers
    - Prevent increased costs to Federal health care programs
    - Ensure replacement drugs are not improperly charged to Federal health care programs



## Post-SAB OIG PAP Opinions

- 2006
  - 06-03 Manufacturer-Sponsored PAP, Outside Part D
  - 06-04 Independent Charity Model
  - 06-08 Free Clinic
  - 06-09 Independent Charity Model
  - 06-10 Independent Charity Model
  - 06-13 Independent Charity Model
  - 06-14 Manufacturer-Sponsored PAP, Outside Part D
  - 06-19 Manufacturer-Sponsored PAP, Outside Part D
  - 06-21 Manufacturer-Sponsored PAP, Outside Part D
- 2007
  - 07-04 Manufacturer-Sponsored PAP, Outside Part D
  - 07-11 Independent Charity Model
  - 07-18 Independent Charity Model
- 2008
  - 08-01: Partnership Bulk Replacement
  - 08-04: Hemophilia A Trial Sample Program
  - [04-15]: Modification of non-profit charitable model

## Recent Advisory Opinions:
08-01 Partnership Bulk Replacement

- Program
  - Non-profit, tax-exempt corporation serves as a liaison between manufacturers and free clinics, FQHCs.
  - The "Partnership" manages bulk replacement product donations from participating manufacturers.
  - Patient eligibility
    - Income test: 200% FPL
    - No prescription drug insurance (no Medicaid, Medicare Part D)
- Process
  - Partnership determines which clinics may participate (pharmacy license, technology considerations)
  - Manufacturers provide initial free supply to clinics/FQHCs
  - Clinics/FQHCs document patient eligibility, dispense product, invoice Partnership
  - Partnership invoices manufacturers
  - Manufacturers ship bulk replacement product directly to clinic/FQHC
  - Partnership audits clinics/FQHCs annually



## Recent Advisory Opinions:
08-01 Partnership Bulk Replacement

- Overall Analysis
  - First, opinion only relates to the Partnership, and not to manufacturers' bulk replacement PAPs.
  - "[W]hile nothing in the request suggests that the PAPs are problematic, we have insufficient information about them to determine whether they are, in fact, properly structured."
- Free Clinic Analysis:
  - Two concerns
    - Does the arrangement induce clinics to purchase manufacturers' products?
      - Neither the clinics nor the Partnership are compensated for prescribing or dispensing drugs
      - Clinics do not benefit financially because they do not bill for services.
      - Clinics receive no financial relief because not obligated to provide care.
      - There is benefit to the clinic, but the benefit inures to the public good.



## Recent Advisory Opinions:
08-01 Partnership Bulk Replacement

    - Does the arrangement influence physician prescribing patterns of clinic physicians with respect to products payable by Federal health care programs?
      - The compensation arrangement between the clinics and the physicians does not incentivize physicians to prescribe drugs available under the arrangement.
  - FQHC Analysis:
    - Same concerns as with clinics, but greater because FQHCs bill Federal health care programs
    - Several factors mitigate AKS risk:
      - Minimal excess stock (monthly shipments)
      - Arrangement is transparent
      - Manufacturers do not control which FQHCs participate
      - Physicians are not compensated based on prescribing patterns
      - FQHCs and participating manufacturers are adequately separated
        - » Conflict of Interest policy
        - » Manufacturer marketing representatives restricted from discussing the arrangement with FQHCs.

## Recent Advisory Opinions:
08-04: Hemophilia A Trial Sample Program

- Program
  - Manufacturer of a recombinant antihemophiliac factor VIII A product provides a free trial supply of product to new patients, including Medicare and Medicaid patients
  - Medicare Part B coverage is available
- Process
  - Manufacturer provides enrollment forms to Hemophilia Treatment Centers (HTCs) and physician offices
    - Limited to 10% of a physician's patients or 20 per year
  - Physicians and patients complete the forms, mail form and prescription to program administrator
  - Program administrator processes prescription and ships drug to patient.



## Recent Advisory Opinions:
08-04: Hemophilia A Trial Sample Program

- Analysis
  - Arrangement carries a low risk of fraud and abuse
  - Two Concerns
    - Does the arrangement constitute a kickback from the manufacturer to the physician?
      - Unlikely because the drug goes directly to the patient and not the physician. No direct or indirect remuneration to the physician.
    - Does the arrangement induce patients to use the drug in the future?
      - The arrangement does not create any costs for Federal health care programs.
      - Lack of on-going financial assistance and significant beneficiary cost-sharing guards against overutilization.
      - Drug itself is not prone to overutilization.



## Recent Advisory Opinions:
(04-15): Modification of Non-Profit Charitable Foundation Model

- AO originally issued 10/29/04
  - Non-profit charitable organization, operating a PAP to provide grants to financially-needy patients suffering from specific chronic or life-threatening diseases
  - Assists with the cost of prescription drugs
  - Revision would to the following:
    - Provide donors with monthly aggregate applicant data including the number of applicants & qualified applicants in particular disease categories. No individual patient information, no information that would enable a donor to correlate the amount or frequency of its donations with the medical condition or number of patients that use its products or services, or the volume of those products or services.
    - Modify its standard donation agreement to permit donors to change or terminate their contributions without cause upon 120 days prior written notice. (Currently, donors commit to participate for at least three years.)
    - Expand the Requestor's existing disease categories

## Recent Advisory Opinions:
(04-15): Modification of non-profit charitable model

- OIG approved of the modifications
  - "[W]e conclude that the three modifications would not affect our conclusion in OIG Advisory Opinion No. 04-15."
- OIG determined that the revised arrangement:
  - No grounds for imposition of civil monetary penalties
  - Potential AKS issue if intent to induce or reward referrals of Federal health care program business
  - No administrative sanctions



## Price Reporting Considerations

- Manufacturers are required to report certain pricing data to certain federal programs
  - Average Manufacture Price (AMP) and Best Price (BP) for Medicaid
  - 340B ceiling price
  - Average Sales Price (ASP) for Medicare Part B
  - Non-Federal Average Manufacturer Price (non-FAMP) for Federal Supply Schedule (FSS)
- There are differences in the types of sales that are included or excluded in these different price reporting systems
- It is critical to understand the requirements for PAP assistance to be excluded. If assistance is included:
  - AMP goes down, BUT
  - BP goes down (potentially to $0)
  - 340B price goes down
  - ASP goes down
  - Non-FAMP goes down



## Medicaid: AMP & BP Exclusions

- The AMP Final Rule (July 17, 2007) provides specific AMP and BP exclusions and *exclusion criteria* for the following types of programs:
  - Patient Assistance Programs
  - Co-Pay Assistance Programs
  - Drug Discount Cards
  - Free Goods
  - Coupons
  - Vouchers
- Correctly characterizing a program vis-à-vis these exclusions is critical to understanding which exception criteria should apply.
- Unfortunately, the exclusions are often poorly defined within the Rule and the question of which exclusion should be applied to various means of offering assistance is largely not addressed in the guidance.

## AMP & BP PAP Exclusion

- PAPs must meet the following four criteria for exclusion:
  "1. The program is focused on extending free products not contingent upon any purchase requirement or extending financial assistance to low income individuals and families, as determined by CMS.
  2. Each manufacturer establishes an amount of the subsidy to be given to individual patients, without any negotiation between the manufacturer and any other third party (such as an insurer or PBM) as to that amount.
  3. The entire amount of the free product or subsidy is made available to the individual patient, without any opportunity for the retail pharmacy or any third party (such as an insurer or PBM), to reduce that subsidy, or take a portion of it, for its own purposes.
  4. The pharmacy collects no additional payment, other than the benefit amount and a bona fide service fee, from the patient assistance program." 72 Fed. Reg. 39,188 (July 17, 2007) (Emphasis added)



## AMP & BP Co-Pay Assistance Program Exclusion

- Co-Pay Assistance Programs
  - Not defined in the rule
    - No specific AMP exclusion in the regulations
  - CMS provides that co-pay assistance programs are "another form of patient assistance programs and should receive similar treatment provided they otherwise qualify for exclusion from AMP under this final rule at § 447.504(h)(12) [the PAP exclusion]."
  - Consider the financial need requirement of the PAP exclusion.
- Distinguish from coupons?



## AMP & BP Drug Discount Card Program

- "Manufacturer-sponsored drug discount card programs"
  - No other description in the Final Rule
  - Potentially a reference to the discount card program that preceded Part D
  - Potentially a reference to savings cards offered by manufacturers
- Separate regulatory exclusion, but in the preamble, CMS refers to PAPs for specific exclusion criteria

## Free Goods Exclusion

- AMP & BP
  - Must be "not contingent on a purchase requirement".
    - "Future purchase"
- ASP
  - Must not be "contingent on any purchase requirement."
- Non-FAMP
  - Must not be "contingent on any written or verbal commercial agreements"
- What does it mean to be "contingent"?



## Other Considerations

- Consider PAP issues when purchasing other manufacturers
  - Ensure due diligence team appreciates the unique AKS issues and pricing issues associated with PAPs
- Consider state anti-kickback statutes and state insurance law vis-à-vis privately insured patients



## Questions?